

Substitute for form 1449/PTO
(Revised 04/2003)

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 3 Attorney Docket Number 033339/234602

O P E R A T I O N S
M A Y 2 5 2 0 0 5
U. S. PATENT AND TRADEMARK OFFICE

Complete if Known

Application Number	09/856,969
Filing Date	August 1, 2001
First Named Inventor	Cayuela et al.
Group Art Unit	1645
Examiner Name	Jana A. Hines

U. S. PATENT DOCUMENTS

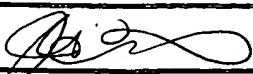
Examiner Initials*	Cite No.	Document Number Number - Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages of Relevant Figures Appear
QH	1	US-5,032,399	07/16/1991	Gorbach et al.	
	2	US-5,413,785	05/09/1995	Nanji	
	3	US-5,591,428	01/07/1997	Bengmark et al.	
	4	US-5,716,615	02/10/1998	Cavaliere Vesely et al.	
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FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.	Foreign Patent Document Country Code - Number Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	English Language Translation Attached
QH	5	EP 0 199 535 A2	10/29/1996	Gorbach et al.		YES
	6	EP 0 861 905 A2	09/02/1998	Pedraglio		YES
	7	EP 0 794 707 B1	09/17/1997	Bouley et al.		NO
	8	WO 98/06411	02/19/1998	Guandalini		YES

OTHER DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	English Language Translation Attached
QH	9	TUOMOLA et al., "Adhesion of some probiotic and dairy <i>Lactobacillus</i> strains to Caco-2 cell cultures", <i>International Journal of Food Microbiology</i> , 41 (1998) pp. 45-51.	YES
	10	YEUNG et al., "Species-Specific Identification of Commercial Probiotic Strains", <i>American Dairy Science Association</i> , Vol. 85, No. 5, 2002, pp. 1039-1051.	YES
	11	MAJAMAA, et al., "Lactic Acid Bacteria in the Treatment of Acute Rotavirus Gastroenteritis", <i>Journal of Pediatric Gastroenterology and Nutrition</i> , 1995, pp. 333-338.	YES

Examiner Signature		Date Considered	01/06
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*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

MAY 25, 2005

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Sheet 2 of 3 Attorney Docket Number 033339/234602

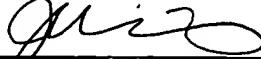
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Application Number 09/856,969
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Group Art Unit 1645
Examiner Name Jana A. Hines

OTHER DOCUMENTS

12	MIETTINEN et al., "Production of Human Tumor Necrosis Factor Alpha, Interleukin-6, and Interleukin-10 is Induced by Lactic Acid Bacteria", <i>Infection and Immunity, American Society for Microbiology</i> , December 1996, pp. 5403-5405.	YES
13	COLLINS, et al., "Deoxyribonucleic Acid Homology Studies of <i>Lactobacillus casei</i> , <i>Lactobacillus paracasei</i> sp. Nov., subsp. <i>Paracasei</i> and subsp. <i>tolerans</i> , and <i>Lactobacillus rhamnosus</i> sp. Nov., comb. Nov." <i>International Journal of Systematic Bacteriology</i> , April 1989, pp. 105-108.	YES
14.	KAILA et al., "Viable versus inactivated lactobacillus strain GG in acute rotavirus diarrhea", <i>Archives of Disease in Childhood</i> , 1995, pp. 51-53.	YES
15	PERDIGON et al., "Immunoadjuvant activity of oral <i>Lactobacillus casei</i> : influence of dose on the secretory immune response and protective capacity in intestinal infections", <i>Journal of Dairy Research</i> (1991), PP. 485-496.	YES
16	SHIBOLET, et al., "Variable Response to Probiotics in Two Models of Experimental Colitis in Rats", <i>Inflammatory Bowel Diseases</i> , 2002, pp. 399-406.	YES
17	VSL #3 product information, www.vslpharma.com	YES
18	ISOLAUERI et al., "Oral Bacteriotherapy for Viral Gastroenteritis", <i>Digestive Diseases and Sciences</i> , Vol. 39, No. 12 (December 1994), pp. 2595-2600.	YES
19	MAJAMAA et al., "Probiotics: A novel approach in the management of food allergy", <i>J Allergy Clin. Immunol</i> , Vol. 99, No. 2, pp. 179-185.	YES
20	BILLER, et al., "Treatment of Recurrent <i>Clostridium difficile</i> Colitis With <i>Lactobacillus GG</i> ", <i>Journal of Pediatric Gastroenterology and Nutrition</i> , 1995, pp. 224-226.	YES
21	MALIN et al., "Promotion of IgA Immune Response in Patients with Crohn's Disease by Oral Bacteriotherapy with <i>Lactobacillus GG</i> ", <i>Ann Nutr Metab.</i> , 1996, pp. 137-145.	YES
22	PELTO et al., "Probiotic bacteria down-regulate the mild-induced inflammatory response in milk-hypersensitive subjects but have an immunostimulatory effect in healthy subjects", <i>Clinical and Experimental Allergy</i> , 1998, Vol. 28, pp. 1474-1479.	YES
23	KORHONEN et al., "Induction of Nitric Oxide Synthesis by Probiotic <i>Lactobacillus rhamnosus</i> GG in J774 Macrophages and Human T84 Intestinal Epithelial Cells", <i>Inflammation</i> , Vol. 25, No. 4, August 2001, pp. 223-232.	YES
24	ISOLAUERI et al., "Probiotics: effects on immunity", <i>Am J Clin Nutr</i> , 2001, 73 (suppl) pp. 444S-450S.	YES
25	BLACKLOW et al., "Viral Gastroenteritis Agents", <i>Viruses, Rickettsiae, and Chlamydiae</i> , pp. 805-812.	YES
26	DUGAS et al., "Regulation by Endogenous Interleukin-10 of the Expression of Nitric Oxide Synthase Induced After Ligation of CD23 in Human Macrophages", <i>Cytokine</i> , Vol. 10, No. 9, September 1998, pp. 680-689.	YES
27	RACHMILEWITZ et al., "Enhanced colonic nitric oxide generation and nitric oxide synthase activity in ulcerative colitis and Crohn's disease", <i>NO generation for IBD</i> , 1995, pp. 718-723.	YES

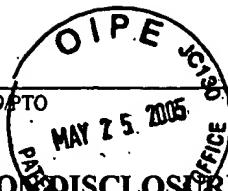
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OTHER DOCUMENTS

28	RACHMILEWITZ et al., "Experimental colitis is ameliorated by inhibition of nitric oxide synthase activity", <i>Gut</i> , 1995, 37, pp. 247-255.	YES
29	KOLIOS et al., "Expression of inducible nitric oxide synthase activity in human colon epithelial cells: modulation by T lymphocyte derived cytokines", <i>Gut</i> , 1998, 43, pp. 56-63.	YES
30	ALVAREZ et al., "Immune system stimulation by probiotics", <i>J Dairy Sci.</i> , July 1995, 78(7), pp. 1597-1606.	YES
31	PERDIGON et al., "Systemic augmentation of the immune response in mice by feeding fermented milks with <i>Lactobacillus casei</i> and <i>Lactobacillus acidophilus</i> ", <i>Immunology</i> , 1988, 63, pp. 17-23.	YES
32	TEJADA-SIMON et al., "Ex Vivo Effects of Lactobacilli, Streptococci, and Bifidobacteria Ingestion on Cytokine and Nitric Oxide Production in a Murine Model", <i>Journal of food Protection</i> , Vol. 62, No. 2, 1999, pp. 162-169.	YES
33	ALICAN et al., "A critical role for nitric oxide in intestinal barrier function and dysfunction", <i>American Physiological Society</i> , 1996, pp. G225-G237.	YES
34	TEPPERMAN et al., "Nitric Oxide Synthase Activity, Viability and Cyclic GMP Levels in Rat Colonic Epithelial Cells: Effect of Endotoxin Challenge", <i>The Journal of Pharmacology and Experimental Therapeutics</i> , Vol. 271, No. 3, 1994, pp. 1477-1482.	YES
35	KORPELA et al., "Lactobacillus rhamnosus GG shows antioxidative properties in vascular endothelial cell culture", <i>Milchwissenschaft</i> , 52(9), 1997, pp. 503-505.	YES
36	DENARIAZ et al., "Immunity and Probiotics", entire manual, 1999.	YES
37	DUGAS et al., "Immunity and Probiotics", <i>Trends Immunology Today</i> , Sept. 1999, Vol. 20, No. 9, pp. 1-4.	YES
38	ISOLAURO, Erika, "Promotion of IgA Immune Response in Patients with Crohn's Disease by Oral Bacteriotherapy with <i>Lactobacillus GG</i> ", <i>Ann Nutr Metab</i> , 1996, 40, pp. 137-145.	YES
39	ISOLAURO, et al., "A Human <i>Lactobacillus</i> Strain (<i>Lactobacillus Casei</i> sp strain GG) Promotes Recovery From Acute Diarrhea in Children", <i>Pediatrics</i> , Vol. 88, No. 1, July 1991, pp. 90-97.	YES
40	DUGAS et al., "Nitric oxide production by human monocytes: evidence for a role of CD23", <i>Immunology Today</i> , Vol. 16, No. 12, 1995, pp. 574-580.	YES
41	Danone World Newsletter, October 1995.	YES
42	SOLIS PEREYRA et al., "Induction of Human Cytokines By Bacteria Used in Dairy Foods", <i>Nutrition Research</i> , Vol. 13, 1993, pp. 1127-1140.	YES
43	EP Communication for Application No. 00909291.7.	YES

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6/10/06

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